**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k052108

**B. Purpose for Submission:**

This is a new device for glucose measurement configured with a blood pressure monitor system which has been previously cleared (k042138).

**C. Measurand:**

Glucose and Blood Pressure

**D. Type of Test:**

Quantitative Glucose Oxidase

Blood Pressure – Non-invasive Oscillometric

**E. Applicant:**

SEIN Electronics Co., Ltd

**F. Proprietary and Established Names:**

Sein Blood Glucose and Blood Pressure Monitor System, Model BGP-100

**G. Regulatory Information:**

1. Regulation section:

   21 CFR §862.1345, Glucose Test System

   21 CFR §862.1660, Quality Control Material (assayed and unassayed)

   21 CFR §870.1130, Noninvasive blood pressure measurement system

2. Classification:

   Class II (Glucose Test System)
   Class I, reserved (Assayed Quality Control Materials)
   Class II (Blood Pressure Measurement System)

3. Product code:

   NBW, CGA – Glucose Test System
   JJX – Single (specified) analyte controls (assayed and unassayed)
   DXN – Blood Pressure Measurement System

4. Panel:

   75, Clinical Chemistry – Glucose Test System and Quality Control Material
   74, Cardiovascular – Blood Pressure Measurement System

**H. Intended Use:**

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   The BGP-100 blood glucose and blood pressure measurement system consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (in Vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.

   Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and oscillometric method of measurement.

3. Special conditions for use statement(s):

   This device is not intended for use on neonates.

   For in vitro diagnostic over-the-counter and professional use

4. Special instrument requirements:

   Sein Blood Glucose and Blood Pressure Monitor System, Model BGP-100

## I. Device Description:

This device combines the functions of a blood glucose meter and a blood pressure measurement system in one unit. Supplied with the meter are the test strips, lancets, lancing device, control solutions and storage case. To measure blood glucose, the user inserts a test strip. A numerical code appears on the screen and the user compares this number to the number located on the test strip bottle to ensure the two numbers match. Once the user confirms that the code number in the meter matches the strip bottle, glucose testing can proceed. The sponsor has provided instructions and illustrations explaining that the blood drop will be pulled into the strip sample entry by capillary action and that the confirmation window must be completely filled with blood to obtain an accurate result. Results are stored in the meters memory for tracking purposes. The blood pressure monitor system was previously cleared (k042138). The controls can be purchased separately.

To measure blood pressure, the user is instructed to wrap the cuff around the left wrist with the palm facing up approximately ¼ to ½ inch below the ball of the thumb. The user is instructed not to move or talk during the measurement. The sponsor has also provided instructions and illustrations explaining that the user must be sitting and the blood pressure cuff must be at the same level as the user's heart to obtain an accurate reading. Results are stored in the meters memory for tracking purposes.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Clever Chek TD-3213
   One Touch Ultra Blood Glucose monitoring system
   Blood pressure Monitor, Model SE-311

2. Predicate 510(k) number(s):

   k042795, k002134, k042138, respectively

3. Comparison with predicate:

| **Similarities – Glucose Meter** | | |
|---|---|---|
| Item | Device | Predicate |
| Specimen | Same | Capillary Whole Blood |
| Methodology | Same | Electrochemical, Glucose Oxidase |
| Measuring Range | Same | 20 -600 mg/dL |
| Display | Same | Direct Readout; no calculation required |
| Alternate Site Testing | Same | Specimen may be taken from fingertip only |
| Power Source | Same | Two 1.5V AAA batteries |

| Differences – Glucose Meter | | |
|---|---|---|
| Item | Device | Predicate |
| Number of readings Stored in Memory | 150 | 352 |
| External Output | USB | Standard RS232 PC interface |
| Reaction time count down | Auto (5 seconds) | Auto (10seconds) |

| Similarities – Blood Pressure Monitoring System | | |
|---|---|---|
| Item | Device | Predicate |
| Type of Reading | Same | Non-invasive, diastolic and systolic blood pressure and pulse rate |
| Location of Reading | Same | Wrist |
| Stethoscope | Same | Not Required |
| Power Source | Same | Two 1.5V AAA batteries |

| Differences – Blood Pressure Monitoring System | | |
|---|---|---|
| Item | Device | Predicate |
| Measuring Range | 20-300 mm Hg | 30-280 mm Hg |
| Pulse Rate | 40-200 beats/min | 40-199 beats/min |
| Cuff Circumference | 5.11–8.26 inches | 5.25-7.75 inches |
| Number of Readings Stored in Memory | 60 | 352 |

**K. Standard/Guidance Document Referenced (if applicable):**

CLSI/NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

CLSI/NCCLS EP6-P; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Proposed Guideline

CLSI/NCCLS EP7-P; Interference Testing in Clinical Chemistry; Proposed Guideline

CLSI/NCCLS GP14-A; Labeling of Home-Use in Vitro Testing Products; Approved Guideline

CLSI/NCCLS C30-A; Ancillary (Bedside) Blood Glucose Testing

IEC 61000-4-2 / 1995; Electromagnetic Compatibility (EMC) - Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test-Edition 1.2; Edition 1:1995 Consolidated with Amendments 1:1998 and 2:2000

IEC 61000-4-3 / 2002; Electromagnetic Compatibility (EMC) - Part 4-3: Testing and Measurement Techniques - Radiated, Radio-Frequency, Electromagnetic Field Immunity Test-Edition 2.1; Edition 2:2002 Consolidated with Amendment 1:2002

EN 60601-1-30 / 1999 / 2001/ 1996; Medical electrical equipment - Part 2: Particular general requirements for the safety

EN 61010-1-2 / 2001; Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements

EN 61326; Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements-Includes Amendment A1: 1998, A2:2001 and A: 2003; IEC 61326:1997 + A1:1998 + A2:2000

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005

FDA Guidance for Industry In Vitro Diagnostic Glucose test System. July 1998

**L. Test Principle:**

Glucose: the glucose oxidase in the strip reacts with the glucose in the sample to produce an electrical current proportional to the glucose concentration. The meter measures the current and converts it to the corresponding glucose concentration in mg/dL or mmol/L.

Blood pressure: the pressure sensor in the cuff detects small changes in pressure and converts them to electrical signals. The meter analyzes the singles and converts them to standard measurements of pulse rate and systolic and diastolic blood pressure.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

The sponsor evaluated the intra precision of the device by running 5 whole blood specimens of different concentration (30-400 mg/dL) within one run using 10 meters. The acceptance criterion is SD < 7.7 mg/dL for glucose values <100 mg/dL and CV <7.5% for glucose values ≥ 100 mg/dL. The results are presented in the table below:

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| N | 100 | 100 | 100 | 100 | 100 |
| Grand Mean (mg/dL) | 42.1 | 98.0 | 141.9 | 207.6 | 336.5 |
| Pooled SD | 1.9 | 3.0 | 5.0 | 7.1 | 12.2 |

The Inter Precision was evaluated by running 5 control solutions of different concentrations (30-400 mg/dL) once a day for 10 days using 9 meters. Acceptance criteria is a CV<10%. The results are presented in the table below:

Inter Precision Study

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| N | 90 | 90 | 90 | 90 | 90 |
| Mean (mg/dL) | 44.1 | 84.5 | 134.7 | 208.5 | 352.5 |
| SD | 2.3 | 2.4 | 6.3 | 7.9 | 19.4 |
| %CV | 5.2 | 2.8 | 4.7 | 3.8 | 5.5 |

Accuracy was based on the ISO International Standard 15197. Acceptable accuracy for results shall be: 95% of the individual results shall fall within $\pm$15 mg/dL at glucose concentration <75 and within 20% at glucose concentration $\geq$75 mg/dL. Three hundred and four (304) capillary blood samples were collected and run on the BGP -100 glucose meter and then run on the reference method (YSI 2300). The sample range was from 26 to 530 mg/dL. Results are shown in the tables below:

Accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

| Within $\pm$ 5 mg/dL (Within $\pm$ 0.28 mmol/L) | Within $\pm$ 10 mg/dL (Within $\pm$ 0.56 mmol/L) | Within $\pm$ 15 mg/dL (Within $\pm$ 0.83 mmol/L) |
|---|---|---|
| 40/44 (90.9%) | 44/44 (100%) | 44/44 (100%) |

Accuracy results for glucose concentration $\geq$75 mg/dL (4.2 mmol/L)

| Within $\pm$ 5 % | Within $\pm$ 10 % | Within $\pm$ 15 % | Within $\pm$ 20% |
|---|---|---|---|
| 178/260 (68.5%) | 232/260 (89.2%) | 248/260 (95.4%) | 259/260 (99.6%) |

A linear regression was also performed and has the following results, y= 1.047x + 4.4358, r =0.994, n=250.

*b. Linearity/assay reportable range:*

The linearity of the glucose measurements was demonstrated by comparing prepared blood samples on the Sein Blood Glucose meter and a glucose reference method (YSI). The nine samples ranged in concentration from a low of approximately 19 mg/dL to a high of approximately 700 mg/dL. The test results of all values, except for the 700 mg/dL, satisfy the ISO International Standard 15197. Acceptable accuracy for results shall be: 95% of the individual results shall fall within $\pm$15 mg/dL at glucose concentration <75 and within 20% at glucose concentration $\geq$75 mg/dL. The linear regression equation obtained with samples ranging from 18 to 108 mg/dL was Y = 0.9894X – 13.3, $R^2$ = 0.9989 and the linear regression equation obtained with samples ranging from 19 to 600 mg/dL was Y = 1.0X – 21.35, $R^2$ = 0.999.

The reportable range for glucose measurements is 20-600 mg/dL.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Two levels of control material are provided for use with the test system and are traceable to NIST and NBS standards. Values are assigned to the controls by comparing to a glucose reference method. Stability is assessed by performing real-time studies for the shelf life and in use stability. Stability is evaluated with the criterion that all values fall with the established range during the time period tested. Shelf life is 18 months and in use stability is 90 days when stored between 8 – 30 ºC.

*d. Detection limit:*

20 mg/dL – See linearity study above.

*e. Analytical specificity:*

Specificity of the glucose meter was assessed by spiking various endogenous and exogenous compounds into prepared whole blood samples. The sponsor first prepared a low whole blood control at approximately 80 mg/dL and a high whole blood control at approximately 200 mg/dL glucose and confirmed these concentrations prior to the addition of the interferents. The sponsor then added the interfering substance and ran each control solution on the BGP-100 system. If the change in glucose measurement from the control solution was less the 15% this was considered no interference. Results of the testing were as follows:

| Interferent | Highest Concentration Where No Interference Seen (mg/dL) |
|---|---|
| Acetaminophen | 20 |
| Ascorbic Acid | 30 |
| Bilirubin | 20 |
| Dopamine | 15 |
| L-dopa | 5 |
| Methyldopa | 3 |
| Tolbutamide | 150 |
| Triglycerides | 3000 |
| Uric Acid | 80 |

The meter was tested at different altitudes to assess the effect of low oxygen levels on the meter performance. No effect on performance was found when three different levels of blood were tested up to 10,000 ft., higher elevations were not tested. The sponsor presented data that supported using the test system between 10ºC to 40ºC.

Hematocrit Effect:

The effect of sample hematocrit variation on the BGP-100 test system was tested experimentally by preparing samples of known hematocrit and spiking aliquots of these samples with four different levels of glucose. These samples were run on the BGP-100 and YSI; there was less than a ±15% bias across the claimed range of 20~60% Hematocrit.

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

See clinical studies section below.

*b. Matrix comparison:*

Not applicable. The glucose meter is intended to be used with capillary whole blood from the finger only.

3. Clinical studies:

Two separate clinical studies of the BGP-100 System performance were performed. The results of these studies are presented in the Clinical Sensitivity section below.

The consumer study was performed at two POC sites with a total of 110 lay-users. The lay-users ranged in age, education and were about equally divided between males and females. Each participant performed their own fingerstick and tested their blood using the instructions in the User's guide. A trained professional then performed another fingerstick and tested the blood on the same meter. Blood was collected and measured on an YSI analyzer.

Another study was performed by Health care professionals at three POC sites. Fifty patient volunteers participated at each site. A fingerstick was performed for testing on the BGP-100 and blood was collected for testing on the YSI analyzer.

*a. Clinical Sensitivity:*

Lay-User study results:

| Site | Number of samples | BGP-100 vs. YSI | r value | Sample Range (mg/dL) | % Clake Error Grid | |
|---|---|---|---|---|---|---|
| **Consumer Results** | | | | | A | B |
| 1 | 53 | y = 0.79x + 23.60 | 0.867 | 60 -200 | 96.2% | 3.8% |
| 2 | 57 | y = 0.91x + 9.18 | 0.960 | 50 – 200 | 98.2% | 1.8% |
| Sum | 110 | y = 0.860x +15.16 | 0.927 | 70-200 | 95% | 5% |
| **Professional Results** | | | | | | |
| 1 | 53 | y = 0.94x + 3.32 | 0.959 | 60 -200 | 98.1% | 1.9% |
| 2 | 57 | y = 0.99x – 0.84 | 0.992 | 50 – 200 | 100% | 0% |
| Sum | 110 | y = 0.976x + 0.583 | 0.979 | 70-200 | 99.1% | 0.9% |

Point-of-Care study results:

| Each Site (n=50) | BGP-100 vs. YSI | r value | Sample Range (mg/dL by YSI) | %Clarke Error Grid | |
|---|---|---|---|---|---|
| | | | | A | B |
| POC 1 | y = 1.08x - 1.7 | 0.991 | 50-350 | 100% | 0% |
| POC 2 | y = 1.06x + 5.0 | 0.991 | 40-350 | 96% | 4% |
| POC 3 | y = 1.06x + 6.6 | 0.995 | 60-480 | 98% | 2% |

*b. Clinical specificity**:***

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The expected values provided in the package insert are referenced from: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual, Philadelphia: Lea and Febiger (1989), 138.

The normal fasting adult glucose range for a non-diabetic is 70 -110 mg/dL. One-hour after a meal, normal blood glucose results should be less the 160 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

**N. Instrument Name:**

Sein Blood Glucose and Blood Pressure Monitor System, Model BGP-100

**O. System Descriptions:**

1. Modes of Operation:

   Each test strip is single use and must be placed replaced with a new strip for additional readings. There are no disposable components used to measure blood pressure.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

   Each bottle of test strips as a code number which is used to calibrate the meter. The user confirms that the code number on the test strip bottle matches the code number in the instrument. If they are different then the user changes the number by depressing the code key on the meter until the correct number is displayed. No further calibrations are required of the user.

6. Quality Control:

   The sponsor is providing a high and low glucose control solution with this device. To mark the test result as a control the user is instructed to press and hold the C button for three seconds. Check will appear on the display. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.